Decision Memo for Prostate Specific Antigen (Addition of ICD-9-CM 600.00, Hypertrophy (benign) of Prostate Without Urinary Obstruction, as a covered indication) (CAG-00326N)

Decision Summary

CMS has determined that ICD-9-CM diagnosis code 600.00, Hypertrophy (benign) of prostate without urinary obstruction, flows from the existing narrative for conditions for which a Prostate Specific Antigen (PSA) is reasonable and necessary. We shall modify the list of "ICD-9-CM Codes Covered by Medicare Program" in the NCD for PSA by adding code 600.00.

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Decision Memo

This coding analysis does not constitute a national coverage determination (NCD). It states the intent of the Centers for Medicare & Medicaid Services (CMS) to issue a change to the list of ICD-9-CM Codes Covered that are linked to one of the negotiated laboratory NCDs. This decision will be announced in an upcoming recurring update notification in accordance with CMS Pub 100-4, Chapter 16, Section 120.2 and will become effective as of the date listed in the transmittal that announces the revision.

TO: Administrative File: CAG – 326N Addition of ICD-9-CM 600.00, Hypertrophy (benign) of Prostate Without Urinary Obstruction as a covered indication for the Prostate Specific Antigen NCD

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SUBJECT: Addition of ICD-9-CM 600.00, Hypertrophy (benign) of Prostate Without Urinary Obstruction, as a covered indication for the Prostate Specific Antigen NCD

DATE: May 31, 2006

I. Decision

CMS has determined that ICD-9-CM diagnosis code 600.00, Hypertrophy (benign) of prostate without urinary obstruction, flows from the existing narrative for conditions for which a Prostate Specific Antigen (PSA) is reasonable and necessary. We shall modify the list of “ICD-9-CM Codes Covered by Medicare Program” in the NCD for PSA by adding code 600.00.

II. Background

PSA is a tumor marker for adenocarcinoma of the prostate. It is used, in combination with other modalities, for the screening, diagnosis, and monitoring of prostate cancer. Screening uses are outside of the scope of the Prostate Specific Antigen NCD.

III. History of Medicare Coverage

In accordance with section 4554 of the Balanced Budget Act of 1997, CMS entered into negotiations with the laboratory community regarding coverage and administrative policies for clinical diagnostic laboratory services. As part of these negotiations, we promulgated a rule that included 23 NCDs. The rule was proposed in the March 10, 2000 edition of the Federal Register (65 FR 13082) and was made final on November 23, 2001 (66 FR 58788). The final rule called for a 12 -month delay in effectuating the NCDs in accordance with the recommendations of the negotiating committee. Thus, the NCDs became effective on November 25, 2002.

In the laboratory NCDs, CMS determined that specific tests were reasonable and necessary for certain medical indications. These decisions were evidence-based, relying on scientific literature reviewed by the negotiating committee. The NCDs contain a narrative describing the indications for which the test is reasonable and necessary. We also developed a list of ICD-9-CM codes that designate diagnoses/conditions that fit within the narrative description of indications that support the medical necessity of the test. This list is entitled “ICD-9-CM Codes Covered by Medicare,” and includes codes where there is a presumption of medical necessity.

In addition, we developed two other ICD-9-CM code lists. The second list is entitled “ICD-9-CM Codes Denied,” and lists diagnosis codes that are never covered by Medicare. The third list is entitled “ICD-9-CM Codes That Do Not Support Medical Necessity,” and includes codes that generally are not considered to support a decision that the test is reasonable and necessary, but for which there are limited exceptions. Tests in this third category may be covered when they are accompanied by additional documentation that supports a determination of reasonable and necessary.

IV. Timeline of Recent Activities

On April 18, 2006, CMS, in response to an external request, opened a coding analysis item regarding the addition of ICD -9-CM 600.00 to the covered indication code list for the Prostate Specific Antigen NCD. We posted a tracking sheet to the Internet (http://www.cms.hhs.gov/mcd/viewtrackingsheet.asp?id=183) and solicited public comment for 30 days on the appropriateness of adding code 600.00 to the list of covered codes for the Prostate Specific Antigen NCD.

We received 11 public comments during the comment period, which ended May 18, 2006. All commenters were supportive of the addition.

V. General Methodological Principles

During the negotiation meetings that led to the development of the 23 clinical diagnostic laboratory NCDs, we stated our intent that the narrative of the NCDs reflect the substance of the determinations. The addition of the coding lists was intended as a convenience to the laboratories and as a means of ensuring consistency among the Medicare claims processing contractors as they interpreted the narrative conditions that support coverage. Thus, all of the codes in the covered code list must flow from the narrative indications of the NCD. We reiterated this position in the November 23, 2001 final rule (66 FR 58795) and in subsequent implementing instructions (Program Memorandum AB-02-110).

On February 25, 2005, we announced in a final notice in the Federal Register (70 FR 9355) that we would maintain the accuracy of the coding lists without substantive changes to the narrative policy through an abbreviated process that did not require scientific evidence. We call this abbreviated process the Coding Analysis for Laboratories (CAL).

VI. CMS Analysis

The "ICD-9-CM Codes Covered by Medicare" list is intended to contain only those codes that flow from the narrative of the indication in the NCD. The Prostate Specific Antigen NCD narrative includes the following text:

“PSA is of proven value in differentiating benign from malignant disease in men with lower urinary tract signs and symptoms…as well as with patients with palpably abnormal prostate glands on physician exam...”

The Stedman’s Medical Dictionary (23rd edition) definition of “sign” includes the following:

“1. Any abnormality indicative of disease, discoverable by the physician at his examination of the patient…”

Prostatic hypertrophy is a lower urinary tract sign and is also a palpable abnormality of the prostate. We believe that the ICD-9-CM code 600.00 Hypertrophy (benign) of prostate without urinary obstruction, flows from the narrative indication statement quoted above.

We intend to issue a recurring update to the edit module implementing the NCDs to add ICD-9-CM code 600.00 to the list of the ICD-9-CM codes covered for the Prostate Specific Antigen NCD.

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